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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,851	03/21/2002	Philippe Msika	REGIM-012	2236

7590 07/28/2004

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EXAMINER	
FLOOD, MICHELE C	
ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,851	MSIKA ET AL.	
	Examiner	Art Unit	
	Michele Flood	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-60* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ___.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendments filed on May 5, 2004. Acknowledgment is made of Applicant's cancellation of Claims 1-31, and newly added Claims 32-60.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 32-60 are under examination.

Response to Arguments

Claim Rejections - 35 USC § 112

Newly added Claims 59 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 59 is rendered vague and indefinite by the phrase "wherein the plant oil product comprises a food additive" because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, does Applicant mean that the at least one plant product comprising the instantly claimed pharmaceutical composition is a food additive or does Applicant mean that the instantly claimed pharmaceutical composition further comprises a food additive. The lack of clarity renders the claim very confusing and ambiguous.

Claim 60 is rendered vague and indefinite by the phrase "wherein the plant product is present in a food in a proportion of between about 0.1% and about 20% by weight relative to the total weight of the food because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, does Applicant mean that the plant oil product is derived from a food product, such as the plants of the avocado or sunflower or soyabean, and that the plant oil product is present in the claim-designated amounts within the plants? Or, does Applicant intend to direct the subject matter of the invention to a method of skin treatment comprising administering a composition comprising at least one plant product and further comprising a food? The lack of clarity renders the claim very confusing and ambiguous.

Claim Rejections - 35 USC § 102

Claims 32-36, and 41-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Laigneau et al. (BA, FR 2692783). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Applicant claims a method for increasing the synthesis of skin lipid comprising administering to a subject a composition comprising at least one plant oil product selected from the group consisting of oil distillates of plant oil, unsaponifiable materials from plant oil, furan lipids of plant oil and mixtures thereof.

Laigneau teaches the instantly claimed invention. For instance, Laigneau teaches the application of compositions that are useful for application to the skin, and as a nutritional supplement, and to treat the effects of UV- A on the skin. Laigneau further

teaches a method of making a composition comprising the unsaponifiable fraction of sesame oil mixed with one or more unsaponifiable fractions from any other vegetable oil, *e.g.*, soya oil and wheat germ oil. For example, Laigneau teaches a composition comprising the unsaponifiable fraction of wheat germ oil and the unsaponifiable fraction of sesame oil, which where obtained by molecular distillation of the plant oils (*see* page 6, line 22 to page 7, line 21). On page 9, lines 1-24, Laigneau teaches that the sesame seed oil comprises linoleic acid (a furan derivative), unsaponifiable fractions, and sterols. Laigneau also teaches that the wheat germ oil comprises unsaponifiable fractions, and sterols (campesterol, stigmasterol, and β-sitosterol), on page 9, line 26 to page 10, line 5. Laigneau further teaches adding the unsaponifiable fractions of plant oils to a physiologically acceptable carrier for the preparation of cosmetic compositions, such as an emulsion, ointment, lipstick, a solar product or restructuring nutritive, anti-wrinkle or day cream. Laigneau does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Laigneau is a one-step process for the administration of a composition comprising the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Laigneau.

The reference anticipates the claimed subject matter.

Claims 32-37 and 41-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Montaudoin et al. (BB, FR 2762512). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Montaudoin teaches a method of orally or topically administering a composition comprising lupin oil optionally with wheat germ oil or a fraction of wheat germ oil, which has antioxidant and anti-elastase action, for protecting skin against damage due to external influences (UVA, UVB, infrared and pollutants) and the effects of aging (wrinkles and loss of skin firmness). The lupin oil was obtained from *Lupinus albus* seeds or flour by solvent extraction, and the resultant oil was subjected to molecular distillation to yield an oil comprising unsaponifiable plant material, which may be subjected concentrated by saponifying the mixture and eliminating salts by concurrent extraction to obtain a residue containing sterols and tocopherols. *See* page 6, line 20 to page 10, line 22. On page 24, in Table 8, Montaudoin also teaches other plant oils which can be used in the making of the referenced compositions, *e.g.*, sunflower oil (tournesol). Montaudoin does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Montaudoin is a one-step process for the administration of a composition comprising the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Montaudoin.

The reference anticipates the claimed subject matter.

Claims 32-36, 38, 41, 42 and 44-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Rancurel (BC, FR 2653974). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Rancurel teaches a method of administering a composition comprising a fraction of soya oil and/or avocado oil, which is combined with a pharmaceutically acceptable medium for the preparation of capsules and dietary products to provide a method retarding aging of the skin and to regenerate conjunctive tissues. Rancurel teaches that the plant fractions were obtained by molecular distillation of the oils and collecting the distillates. In an example, Rancurel teaches subjecting the plant oils to molecular distillation to obtain a first distillate containing triglycerides, and removing the triglycerides to obtain a fraction enriched in non-saponifiable components, such as sterols and tocopherols, *etc.* Finally, Rancurel teaches mixing the fractions of soya oil and avocado oil. The products taught by Rancurel have an antagonistic effect with respect to cholesterol and fats, also. The reference anticipates the claimed subject matter. Rancurel does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Rancurel is a one-step process for the administration of a composition comprising the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Rancurel.

Claims 32-36 and 42-59 are rejected under 35 U.S.C. 102(b) as being anticipated by De Froment (BD, FR 2187328). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

De Froment teaches a method of administering compositions that are useful in dermatology cosmetology as an aid to cicatrisation, protection of the skin against sun damage, and for the treatment of ichthyosis. The compositions taught by De Froment comprise unsaponifiable materials from lucerne oil in an amount of 0.5%. *See* page 1 to page 2, line 2 and page 2, lines 37-40. The composition is prepared from dehydrated lucerne by solvent extraction, saponification, and removal of lipids and evaporation. On page 2, lines 6-19, De Froment teaches that the composition contains phytosterols (stigmasterol and sitosterol). De Froment does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by De Froment is a one-step process for the administration of a composition comprising the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by De Froment.

The reference anticipates the claimed subject matter.

Claims 32-34 and 40-59 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber et al. (BF, EP 0775480). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Huber teaches a method of enhancing metabolism of the skin and mucosal tissue, increasing skin thickness, treating aging human skin, and reversing dermal atrophy known to be associated with human skin photoaging comprising administering a composition comprising an extract of avocado seed or avocado pit, which contains lipid furans. *See* page 3, line 56 to page 6, line 16. The composition taught by Huber is combined with a pharmaceutically carrier, which is topically applied to skin for the treatment of skin disorders. Huber further teaches the oral administration of the reference composition. For example, Huber teaches that the referenced composition comprising furan has profound and beneficial effects on the epidermis and dermis of the skins, significantly moisturizes and smoothes the skin, and enhances the metabolism of skin, on page 4, lines 20-54. Huber does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Huber is a one-step process for the administration of a composition comprising the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Huber.

The reference anticipates the claimed subject matter.

Claims 32-34, 38, 41-44 and 51-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Khaiat (BG, EP 0643960). The rejection stands for the reasons set forth in the previous Office action and for the reasons set forth below.

Khaiat teaches a method of administering compositions that are effective in treating areas of dry and/or greasy skin. The compositions taught by Khaiat comprise an unsaponifiable faction of soya oil or karate nut butter, a fatty acid triglyceride (obtained from olive oil or sweet almond oil); and, a hydrolysate of soya or wheat proteins, which are mixed with a pharmaceutically acceptable medium. Khaiat does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Khaiat is a one-step process for the administration of a composition comprising the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Khaiat.

The reference anticipates the claimed subject matter.

Claims 32, 33, 35, 38 and 41-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Aron-Bruntiere et al. (BJ, FR 2405068). Newly applied as necessitated by amendment.

Aron-Bruntiere teaches the instantly claimed invention. For instance, Aron-Bruntiere teaches topically administering to skin water in oil emulsions comprising an unsaponifiable fraction of plant oil (*e.g.*, avocado oil and soya oil; *see* Claims 4 and 5 of the patent) containing stigmasterol and alpha-tocopherol. Note that the ingredients avocado oil and soya oil are read as a food additive for humans and/or animals; and, that the food additives taught by Aron-Bruntiere are present in the same claim-

designated amounts of a food additives, as instantly claimed by Applicant. The compositions taught by Aron-Bruntiere are applied to conjunctive tissue for the treatment of dry skin conditions, have anti-scleroatrophic action, prevent formation of toxic peroxides, and stimulate renewal of the epidermis and normalizes formation of corneal cells in the sebaceous pores. Aron-Bruntiere does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Aron-Bruntiere is a one-step process for the administration of a composition comprising the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Aron-Bruntiere.

The reference anticipates the claimed subject matter.

Claims 32-34, 39, 41-44, 47-53 and 57-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Guillon (A1, US 4,386,067). Newly applied as necessitated by amendment.

Guillon teaches the instantly claimed inventions. For instance, Guillon teaches a method of administering to human skin a composition comprising a non-saponifiable fraction of avocado oil and a non-saponifiable fraction of soya-bean oil. *See* Column 2, line 53 to Column 3, line 3, wherein Guillon teaches that the reference composition for topical application to the skin comprising the same ingredients and the same ratio and percentage amount as instantly claimed by Applicant. Note that the ingredients

avocado oil and soya oil are read as a food additive for humans and/or animals; and, that the food additives taught by Guillon are present in the same claim-designated amounts of a food additive, as instantly claimed by Applicant. Guillon does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Guillon is a one-step process for the administration of a composition comprising the same ingredients, and the same amount of the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Guillon.

The reference anticipates the claimed subject matter.

Claims 32-36 and 41-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Sekimoto et al. (O). Newly applied as necessitated by amendment.

Sekimoto teaches the claimed inventions. For instance, Sekimoto teaches a method of administering a composition comprising sitosterol obtained from various vegetable oils for the treatment of dry skin and keratinisation and softening of plantar skin. The composition taught by Sekimoto comprises 0.3% sitosterol or 2.0% of sitosterol-containing vegetable oils. Note that the ingredient vegetable oil comprising sitosterol is read as a food additive for humans and/or animals; and, that the food additives taught by Sekimoto are present in the same claim-designated amounts of a food additive, as instantly claimed by Applicant. Sekimoto does not expressly teach that

the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Sekimoto is a one-step process for the administration of a composition comprising the same ingredients, and the same amount of the same ingredients, as instantly claimed by Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Sekimoto.

The reference anticipates the claimed subject matter.

Claims 32-34 and 41-60 are rejected under 35 U.S.C. 102(b) as being anticipated by Inoue et al. (N). Newly applied as necessitated by amendment.

Inoue teaches the claimed invention. For instance, Inoue teaches a method for the topical application to skin a bath composition comprising a non-saponifiable from rice bran oil, *i.e.,* γ-orzanol, in an amount of 2.0% of the total weight of the reference composition for the treating atopic dermatitis or xeroderma. Note that the vegetable oils comprising γ-orzanol are read as food additives for humans and/or animals; and, that the food additives taught by Inoue are present in the same claim-designated amounts of a food additive, as instantly claimed by Applicant. Inoue does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Inoue is a one-step process for the administration of a composition comprising the same ingredients, and the same amount of the same ingredients, as instantly claimed by

Applicant. Therefore, a method for the treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Inoue.

The reference anticipates the claimed subject matter.

Claims 32-35 and 41-60 are rejected under 35 U.S.C. 102(e) as being anticipated by Moy (B). Newly as necessitated by amendment.

Applicant's claimed invention was set forth above.

Moy teaches a method of preparing a dermatological composition comprising about 5 and 15 weight percent of unsaponifiable avocado seed lipids, in Column 4, lines 25-37. In Column 3, lines 54-61, Moy teaches that the unsaponifiable material of avocado oil contains sterols (stigmasterol, sitosterol and campesterol). The composition taught Moy are used in the making of topical compositions for the skin, which are used for treating skin keratoses or striae distensae, and eliminating or reducing size of skin lesions. Note that the avocado oil unsaponifiable avocado seed lipids is read as food additive for humans and/or animals; and, that the food additive taught by Moy is in the same claim-designated amounts of a food additive, as instantly claimed by Applicant. Moy does not expressly teach that that the reference method for administering the reference composition is effective in each of the instantly claimed skin disease conditions. However, the method taught by Moy is a one-step process for the administration of a composition comprising the same ingredients, and the same amount of the same ingredients, as instantly claimed by Applicant. Therefore, a method for the

treatment of each of the instantly claimed skin disease conditions is inherent to the method taught by Moy.

The reference anticipates the claimed subject matter.

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new grounds of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michele C. Flood

MICHELE FLOOD
PATENT EXAMINER

MCF
July 26, 2004